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Dated: June 2, 2009

Electronic Signature for Elizabeth A. Hanley: /Elizabeth A. Hanley/

Docket No.: 117750-02301  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Malcolm Carter *et al.*

Application No.: 10/528,250

Confirmation No.: 2767

Filed: June 21, 2005

Art Unit: 1624

For: BENZODIAZEPINE DERIVATIVES AND  
PHARMACEUTICAL COMPOSITIONS  
CONTAINING THEM

Examiner: Bruck KIFLE

MS Petitions  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### STATEMENT UNDER 37 C.F.R. § 1.705(b)(2)

Dear Sirs:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Under 37 C.F.R. § 1.705(b)” being filed herewith for the above-referenced patent application. In view of the following, it is respectfully requested that Applicants be granted a Patent Term Adjustment of 370 days.
2. Pursuant to 37 C.F.R. § 1.705(b)(2)(i), Applicants respectfully submit that the correct period of Patent Term Adjustment is 370 days which includes A-delays, B-delays, reductions due to Applicants’ delays, exclusions due to a notice of appeal and a Request for Continued Examination, and overlap between A-delays and B-delays. First, pursuant to 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1), Applicants are entitled to an adjustment of 269 days due to the U.S. Patent and Trademark Office’s (USPTO) failure to mail a notification or notice of allowance prior to 14 months after the date on which the Applicant fulfilled the requirements of 35 U.S.C. §

371 (A-delays). Pursuant to 37 C.F.R. §§ 1.702(a)(4) and 1.703(a)(6), Applicants are also entitled to an adjustment of at least 33 days due to the USPTO's failure to issue the patent within 4 months of payment of the issue fee (A-delays). Pursuant to 37 C.F.R. §§ 1.702(b)(1) and 1.703(b), Applicants are also entitled to an adjustment of 596 days due to the USPTO's failure to issue a patent within 3 years of the commencement of this application under 35 U.S.C. § 371(b) (B-delays). Pursuant to 37 C.F.R. § 1.704 (a), the Patent Term Adjustment is reduced by 31 days due to Applicants' failure to respond to an Office Action within 3 months of the mailing date of the Office Action (Reduction). Pursuant to 37 CFR §§ 1.702(b)(1) and 1.703(b)(1), 349 are excluded from the Patent Term Adjustment due to the filing of an RCE (Exclusion). Pursuant to 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4), 115 days are also excluded from the Patent Term Adjustment due to the filing of a notice of appeal (Exclusion). Pursuant to 35 U.S.C. § 154(b)(2)(A), the Patent Term Adjustment is reduced by 33 days due to overlap of A-delays and B-delays. Accordingly, pursuant to 37 C.F.R. § 1.703(f), Applicants are entitled to a Patent Term Adjustment of 370 days, which is equivalent to the sum of the A-delays and B-delays minus the exclusions, reductions and overlap terms.

3. The relevant dates, pursuant to 37 C.F.R. § 1.705(b)(2)(iii), and the adjustment that the patent will be entitled to, pursuant to 37 C.F.R. § 1.703(f), are set forth as follows:

**A-Delays: USPTO Examination Delays Pursuant to 37 C.F.R. § 1.702(a) and § 1.703(a)**

In the instant application, Applicants note that the Notice of Allowance allotted 269 days of USPTO A-delays. Applicants respectfully submit that this calculation is in error. Applicants note that the 35 U.S.C. § 371 requirements were fulfilled on June 21, 2005. Pursuant to 37 C.F.R. § 1.703(a)(1) Applicants are entitled to a period of adjustment that is equivalent to the number of days beginning on the day after the date that is fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. § 371 and ending on the date of mailing of an action under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151. For purposes of C.F.R. § 1.703(a)(1), the 14-month date is August 21, 2006. Applicants note that the first notification, a Restriction Requirement, was mailed on May 17, 2007. Accordingly, the sum of the days in the period beginning on August 21, 2006 and ending on May 17, 2007 is 269 days of A-delay.

Additionally, it is stated in the notice of allowance that the patent will be issued the on November 3, 2009, which is the Tuesday that immediately precedes the date that is 28 weeks from the mailing date of the notice of allowance. Pursuant to 37 C.F.R. § 1.703(a)(6) applicants are entitled to an adjustment in patent term that is equivalent to the number of days in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued. In the present case, the issue fee will be paid no later than June 2, 2009. For purposes of 37 C.F.R. § 1.703(a)(6), the 4-month date is no later than October 1, 2009. The number of days in the period beginning on October 1, 2009 and ending on November 3, 2009 is 33 days.

Accordingly, the USPTO has accrued a summed total of 302 days of A-delay.

**B-Delays: USPTO Three-Years Delay Pursuant to 37 C.F.R. § 1.702(b) and § 1.703(b)**

In the instant case, the Patent Term Adjustment listed in the Notice of Allowance granted 0 days of B-delays. However, Applicants believe that this Patent Term Adjustment has been made in error. Applicants respectfully note that the national stage of the application commenced on March 17, 2005. The three-year period, for purposes of calculating B-delays, ended on March 17, 2008. Accordingly, pursuant to 37 C.F.R. § 1.703(b), Applicants are entitled to a Patent Term Adjustment that is equivalent to the sum of the number of days in the period beginning on March 17, 2008 and ending on the date that the patent issues. Applicants note that the Notice of Allowance states that the patent will be issued on the Tuesday immediately preceding the date that is 28 weeks from the mailing date of the Notice of Allowance. The Notice of Allowance was mailed on April 22, 2009. Accordingly, the patent will issue no earlier than Tuesday November 3, 2009. The sum of the period beginning on March 17, 2008 and ending on November 3, 2009 is 596 days.

Accordingly, the USPTO has accrued 596 days of B-delay.

**Reduction of Patent Term Adjustment Pursuant to 37 C.F.R. § 1.704(a)**

Applicants note that the notice of allowance attributed 31 days of reduction to the Applicants. Applicants do not dispute this reduction.

**Exclusions From Patent Term Adjustment Pursuant to 37 C.F.R. § 1.703(b)(4)**

As set forth in 37 C.F.R. § 1.703(b)(4), the period of adjustment based on the grounds set forth in 37 C.F.R. § 1.702 excludes the number of days in the period beginning on the date on which a notice of appeal to the Board of Patent Appeals and Interferences (the Board) was filed and ending on the date of the last decision by the Board, or on the date of mailing of an action under 35 U.S.C. § 151, whichever occurs first, if the appeal did not result in a decision by the Board. Applicants filed a notice of appeal on July 29, 2008 and filed a Request for Continued Examination (RCE) on November 20, 2008. Pursuant to 37 C.F.R. § 1.114(d) the filing of an RCE after the filing of a notice of appeal but before a decision is rendered on the appeal, effectively withdraws the notice of appeal. Accordingly, the appeal ended on November 20, 2008. The sum of the period between July 29, 2008 and November 20, 2008 is 115 days.

As set forth in 37 C.F.R. § 1.703(b)(1), the period of adjustment based on the grounds set forth in 37 C.F.R. § 1.702 excludes the number of days in the period beginning on the date on which a RCE of the application under 35 U.S.C. § 132(b) was filed and ending on the date that the patent was issued. The RCE was filed on November 20, 2008. Applicants note that the Notice of Allowance states that the patent will be issued on the Tuesday immediately preceding the date that is 28 weeks from the mailing date of the Notice of Allowance. The Notice of Allowance was mailed on April 22, 2009. Accordingly, the patent will issue no earlier than Tuesday November 3, 2009. The sum of the period beginning on November 20, 2008 and ending on November 3, 2009 is 349 days.

Accordingly, Applicants have accrued a summed total of 464 days of exclusions.

**Overlapping Periods of USPTO A-Delays and B-Delays Pursuant to 37 C.F.R. § 1.703(f)**

As set forth in 37 C.F.R. §1.703(f), the period of adjustment based on the grounds set forth in 37 C.F.R. § 1.702 is the sum of all periods of Examination Delay and the maximum period of Three Years Delay, to the extent these periods of delay are not overlapping. Pursuant to 37 C.F.R. 1.703(f), the period of adjustment will not exceed the actual number of days the issuance of the patent was delayed. Applicants note that the U.S. District Court of D.C. has recently clarified that under 35 USC §154(b)(2)(A) the only way a period of Examination Delay (“A-delay”) and a period of Three-Years Delay (“B-delay”) can “overlap” is if they occur on the same calendar day or days. See *Wyeth v. Dudas*, No. 07- 1492. 2008 U.S. Dist. LEXIS 76063 at 9 (D. D.C. Sept. 30, 2008). In the instant case, the B-delays began on March 17, 2008 and there were 33 days of USPTO A-delays that begun on June 2, 2009 and will end on October 1, 2009. Accordingly, there were 33 days of overlap between A-delays and B-delays.

4. In accordance with 37 C.F.R. 1.705(b)(2)(iii), Applicants submit that the above-referenced application is not subject to a terminal disclaimer.
5. In view of 37 C.F.R. 1.705(b)(2)(iv)(A), Applicants submit that they are unaware of any circumstances during the prosecution of the application, beyond the 31 days already calculated by the USPTO, that would constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.
6. In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that the issued patent reflect a Patent Term Adjustment of 370 days.
7. In accordance with 37 C.F.R. 1.705(b)(2)(i), Applicants submit herewith the fee set forth in 37 C.F.R. 1.18(e). It is Applicants’ understanding that this \$200.00 fee is required for this application for Patent Term Adjustment. However, should any additional fees be necessary, the

Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-4876, under Order No. 117750-02301.

Dated: June 2, 2009

Respectfully submitted,

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